



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Update of the NICEATM-ICCVAM Five-Year Plan: Request for Comments

AGENCY: Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH)

ACTION: Request for Comments

SUMMARY: The NIEHS and the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) request public comments that can be considered by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and agencies' program offices in updating *The NICEATM-ICCVAM Five-Year Plan (2008-2012)* (ICCVAM, 2008). The current plan addresses: (1) identification of areas of high priority for new and revised non-animal and alternative assays to reduce, refine (enhance animal well-being and lessen or avoid pain and distress), and replace the use of animals in testing and (2) research, development, translation, and validation of new and revised non-animal and other alternatives assays for integration of relevant and reliable methods into Federal agencies' testing programs.

DATES: Submit comments on or before January 15, 2012.

ADDRESSES: NICEATM prefers that comments be submitted electronically via the NICEATM-ICCVAM website (http://iccvam.niehs.nih.gov/contact/FR_pubcomment.htm) or via email to niceatm@niehs.nih.gov. Written comments may also be sent by mail or fax to Dr. William S.

Stokes, Director, NICEATM, NIEHS, P.O. Box 12233, Mail Stop: K2–16, Research Triangle Park, NC 27709; (fax) 919–541–0947. Courier address: NICEATM, NIEHS, Room 2034, 530 Davis Drive, Morrisville, NC 27560.

FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes: (telephone) 919-541-2384, (fax) 919-541-0947, or (email) niceatm@niehs.nih.gov.

SUPPLEMENTARY INFORMATION:

Background

Congress established ICCVAM to promote development, validation, and regulatory acceptance of new or revised alternative toxicological test methods that protect human and animal health and the environment while reducing, refining (enhancing animal well-being and lessening or avoiding pain and distress), or replacing animal tests and ensuring human safety and product effectiveness (42 U.S.C. 285l–3). In 2008 NICEATM and ICCVAM published a five-year plan for the years 2008 through 2012. The plan addressed (1) identification of areas of high priority for new and revised non-animal and alternative assays for reduction, refinement, and replacement of animal tests and (2) research, development, translation, and validation of new and revised non-animal and other alternative assays for integration into Federal agency testing programs (ICCVAM, 2008). Progress relevant to the five-year plan can be found in the *Biennial Progress Report: Interagency Coordinating Committee on the Validation of Alternative Methods – 2008-2009* (ICCVAM, 2010) and on the ICCVAM website (<http://iccvam.niehs.nih.gov>). ICCVAM and agencies' program offices are preparing to update the plan and identify goals and priorities for the years 2013-2017.

Request for Public Comments

The NIEHS and NICEATM invite public comments for consideration by ICCVAM and agencies' program offices in updating the current NICEATM-ICCVAM five-year plan. With regard to reducing, refining, and replacing animal use, ICCVAM identified and ranked the types of regulatory safety tests in the 2008-2012 plan that it considered the highest priority for the development and validation of alternative test methods. These priorities were based on the severity of unrelieved pain and distress and the number of animals involved in each type of testing, as well as individual agency's priorities. The priorities were as follows:

- Highest priority testing areas: acute eye irritation and corrosion, acute skin toxicity (including irritation/corrosion, sensitization, absorption), acute systemic toxicity (acute poisoning) -- oral/ dermal/inhalation, and biologics/vaccines.
- Other priority testing areas: immunotoxicity, endocrine disruptors, pyrogenicity, reproductive/developmental toxicity, and chronic toxicity/carcinogenicity.
- Other testing areas of interest: neurotoxicity.

The NIEHS and NICEATM seek public input on the following questions:

1. Do you have comments on the priority areas for the development and validation of alternative test methods listed above?
2. Considering available science and technology, what development, translation, and validation activities are most likely to have the greatest impacts within the next five years on reducing, refining, or replacing animal use in the priority areas?
3. What research and development activities hold the greatest promise in the long-term for reducing, refining, or replacing animal use in the priority areas?

4. What are appropriate measures for evaluating progress in enhancing the development and use of alternative test methods in the priority areas?

Individuals submitting comments should include appropriate contact information (name, affiliation, mailing address, phone, fax, email, and sponsoring organization, if applicable). All comments received by January 15, 2012, will be posted on the NICEATM-ICCVAM website (<http://ntp-apps.niehs.nih.gov/iccvam/b/searchPubCom.cfm>) and identified by the individual's name and affiliation, as well as sponsoring organization, if applicable.

Background Information on NICEATM and ICCVAM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative testing methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological and safety testing methods that more accurately assess the safety and hazards of chemicals and products and that reduce, refine (enhance animal well-being and lessen or avoid pain and distress), or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies applicable to the needs of Federal agencies. Additional information about NICEATM and ICCVAM can be found on the NICEATM-ICCVAM website (<http://iccvam.niehs.nih.gov>).

References

ICCVAM. 2008. The NICEATM-ICCVAM Five-Year Plan (2008-2012). NIH Publication No. 08-6410. Research Triangle Park, NC: National Institute of Environmental Health Sciences. Available: <http://iccvam.niehs.nih.gov/docs/5yearplan.htm>.

ICCVAM. 2010. Biennial Progress Report: Interagency Coordinating Committee on the Validation of Alternative Methods – 2008-2009. NIH Publication No. 10-7612. Research Triangle Park, NC: National Institute of Environmental Health Sciences. Available: <http://iccvam.niehs.nih.gov/about/ICCVAMrpts.htm>.

Dated: November 10, 2011

John R. Bucher, Ph.D.

Associate Director, National Toxicology Program

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